UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA and
THE STATE OF NEW YORK

CIVIL ACTION No. 12-10896-MPK[1]

ex rel. DR. ANTONI NARGOL & DR. DAVID LANGTON,
Relators,

v.

DEPUY ORTHOPAEDICS, INC., DEPUY, INC., and JOHNSON & JOHNSON SERVICES, INC.
Defendants.

MEMORANDUM AND ORDER ON RELATORS' MOTION FOR CLARIFICATION OF PROTECTIVE ORDER (#358) AND DEFENDANTS' MOTION TO COMPEL (#387).

KELLEY, U.S.M.J.

I. Introduction.

In May 2012, relators, Dr. Antoni Nargol and Dr. Robert Langton, brought this qui tam action against defendants, DePuy Orthopaedics, Inc., DePuy, Inc., and Johnson & Johnson Services, Inc. (collectively, DePuy), the makers of various metal-on-metal (MoM) hip replacement devices, under the False Claims Act (the FCA), 31 U.S.C. §§ 3729 *et seq.* and the New York state false claims act. (##1; 204.)[2] At issue is the MoM device DePuy manufactured under its "Pinnacle" product line (the Pinnacle or the Pinnacle device). (#219 ¶ 6.)

[1] With the parties' consent, this case has been assigned to the undersigned for all purposes, including trial and the entry of judgment, pursuant to 28 U.S.C. § 636(c). (#318.)

[2] Previous claims arising under the laws of other states have been dismissed. *See* #204 at 31.

Relators filed an amended complaint under seal in November 2013. (#23.) The Department of Justice (DOJ) declined to intervene on behalf of the United States. (#32.) In May 2015, relators filed a second amended complaint, which was dismissed by the district court, Saylor, J., with prejudice. (##184; 185.) Relators appealed. (#198.) The First Circuit affirmed the district court's decision in part, vacated it part, and remanded the case for resolution of the surviving claims. (#204 at 31); *see U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 43 (1st Cir. 2017).

The case was reopened (#210), assigned to Judge Sorokin (#211), and relators filed a corrected second amended complaint, setting out the surviving claims. (#219.) Relators' corrected second amended complaint alleges that, over a five-year period, DePuy illegally promoted and sold a significant number of Pinnacle MoM devices that fell outside FDA-approved manufacturing specifications, causing false claims to be submitted to Medicare and Medicaid. *See id.* ¶¶ 88, 104, 179–81.

A key issue in this action is that relators previously served as experts in other, multi-district litigation (MDL litigation) involving another MoM hip replacement device manufactured by DePuy, called "ASR," along with the Pinnacle device. The parties filed a stipulated protective order of confidentiality, which was approved by Judge Sorokin on January 8, 2018, to govern relators' use of information they learned as experts in the previous cases. (#249.) Judge Sorokin's order references an earlier order, entered by the Honorable David A. Katz, of the Northern District of Ohio, in the ASR MDL litigation, which expressly states that relators are prohibited from using the information they learned as experts in that litigation in this action. (#103 at 17–18.)

On December 10, 2019, this court entered a scheduling order, setting deadlines for discovery. (##354 at 3–4; 357.) Beginning on December 20, 2019, the parties filed the following motions: (1) relators' motion for clarification, regarding the court's December 10, 2019 scheduling

order and Judge Sorokin's January 8, 2018 protective order (#358); (2) relators' supplemental motion for additional discovery (#361); (3) DePuy's motion to strike portions of relators' corrected second amended complaint and dismiss the case (#368); (4) relators' motion for an order to permit *in camera* production and disclosure of confidential information to potential co-counsel (#373); (5) DePuy's motion for determination of relators' claims of privilege (#379); (6) DePuy's motion to compel discovery (#387); (7) relator's motion to compel discovery (#399); and (8) relators' motion to stay discovery. (#403.)

On March 20, 2020, the court granted relators' motion to stay discovery. (#405.) The court instructed the parties not to file additional motions until further order from the court, apart from outstanding oppositions to any motion to compel and a further response for which leave to file had already been granted. (#406.)

The parties' remaining motions have been fully briefed. *See* ##359; 360; 361; 363; 364; 365; 369; 370; 374; 376; 378; 380; 381; 386; 388; 392; 394; 397; 400; 409; 410; 411.

II. The Facts.

The following facts are taken from relators' corrected second amended complaint, the operative pleading, unless otherwise indicated.

Defendant DePuy Orthopaedics is in the business of designing, manufacturing, and distributing MoM hip replacement devices used to treat medical conditions such as late-stage degenerative hip disease, hip joint damage, and osteoarthritis, among other conditions. (#219 ¶ 73.) It is a wholly-owned subsidiary of defendant DePuy, Inc., which is, in turn, a wholly-owned subsidiary of defendant Johnson & Johnson Services, Inc. *Id.* ¶ 75. Relators, Dr. Antoni Nargol and Dr. David Langton, describe themselves "as two of the most prominent experts in MoM surgical technique and engineering technology[.]" *Id.* ¶ 23. Throughout the 2000s, relators used

DePuy MoM devices such as the Pinnacle and ASR to treat hip conditions in many patients. *See generally id.*[3]

Beginning in 2007, relators conducted a research study on DePuy's ASR, which showed "significantly greater [metal] ion concentrations in" the bloodstream of hip-replacement patients who had used ASR as compared to hip-replacement patients who had used competing non-DePuy devices. (#219 ¶ 31 (citing David Langton et al., *The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip*, J. BONE JOINT SURG. (BRITISH VOLUME) (Sept. 2008)).) Relators assert that this greater concentration of metal ions, present in patients who received the ASR, and later, in patients who received the Pinnacle device, resulted in part from the separate metal components of the devices rubbing against each other. *Id.* ¶¶ 42–43, 168, 175.

Starting in 2010, DePuy "found itself embroiled" in patients' personal injury and products liability lawsuits, primarily related to ASR. *Id.* ¶ 56. According to the corrected second amended complaint, DePuy faces a total of 10,000 lawsuits related to ASR in federal and state courts in California, Ohio, and New Jersey. *Id.* ¶ 57. "In the wake of the ASR lawsuits, more than 5,000

[3] Total hip replacement with MoM devices like the Pinnacle and ASR involves replacing the bone components of a hip joint, the ball (the femoral head) and the socket (acetabulum), with metal components, a femoral head and an acetabular cup. (#219 ¶¶ 145, 147, 149.) The space within a patient's body between the femoral head and the acetabular cup is referred to as the diametrical clearance. *Id.* ¶ 157. Bodily fluid is supposed to fill in the diametrical clearance and prevent the femoral head and acetabular cup from contacting each other. *Id.* ¶ 158. As is typical in many hip replacement devices, the Pinnacle included a metal liner that formed an additional buffer between the femoral head and acetabular cup. (#204 at 4); *DePuy*, 865 F.3d at 32. Also, like other hip replacement devices, components of the Pinnacle replaced the bit of a patient's femur bone directly below the femoral head with a "femoral stem." (#204 at 4.) The top of the femoral stem was connected to a "trunnion" that inserted into a "taper" in the metal femoral head. *Id.* "[T]his union is known as the 'taper trunnion' or the 'taper junction.'" *Id.*

Though relators make various allegations with respect to the ASR device in their corrected second amended complaint, relators make no claims relating to the ASR in the present qui tam action.

personal injury actions have been filed by patients who have been injured by the Pinnacle device. These cases have largely been consolidated into the MDL in the Northern District of Texas" [the Pinnacle MDL]. *Id.* ¶ 58.

The present motions stem from the fact that, prior to this litigation, relators have served as testifying experts or fact witnesses, or otherwise provided expert assistance, in many products liability and personal injury cases against DePuy, *id.* ¶¶ 68, 72, including the ASR MDL and the Pinnacle MDL (collectively the MDL litigations). (#359 at 2 n.1.) In doing so, relators obtained information about DePuy subject to other courts' protective or confidentiality orders. Most significant to this case is an order issued in the ASR MDL litigation by the Honorable David A. Katz in the Northern District of Ohio on January 5, 2015, which provides that relators are "*prohibited* from sharing or using the information they received in their capacities as experts [in that litigation] in [the present qui tam proceeding]. They are also *prohibited* from sharing their information with any third-party, including any government entities, foreign or domestic." (#103 at 18.) (emphasis in original).[4]

According to Judge Katz's order, beginning around May 2012, plaintiffs' counsel in the ASR MDL litigation provided relators with confidential DePuy documents to assist them in preparing for their expert testimony there. *Id.* at 12. During their preparation, relators combined their own personal knowledge with the information they learned from the confidential DePuy documents and concluded that DePuy had violated 31 U.S.C. § 3729. *Id.* Because relators used the confidential DePuy documents, which were subject to Judge Katz's order, to support their

[4] Relators moved to intervene in the ASR MDL, in an attempt to be able to use the confidential information they obtained as experts in the ASR MDL in the present case. (#103 at 11.) In his decision denying the motion to intervene and accompanying order, Judge Katz noted that, as experts, relators agreed to abide by a confidentiality order, previously issued by the court, limiting the use and production of protected documents in the ASR MDL. *Id.* at 11–12, 17–18.

allegations in both the complaint and first amended complaint in this action (#103 at 13), Judge Saylor deemed those documents "tainted" and ordered relators to file a second amended complaint, omitting any allegations that contained any confidential DePuy information. (#104 at 27.) Per Judge Saylor's order, relators were to file affidavits, swearing that they did not use any confidential documents in violation of Judge Katz's order, or any other relevant confidentiality order, in drafting the second amended complaint. *See* #101.

After relators filed the second amended complaint and accompanying affidavits, DePuy moved to dismiss the case pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). (#145 at 1.) Judge Saylor granted DePuy's motion and denied relators' motion for reconsideration; relators appealed to the First Circuit. (##184; 185; 196; 198.) The First Circuit vacated the district court's dismissal of the claims at issue here (whether "DePuy caused physicians to submit claims to the United States and New York for payment for Pinnacle MoM devices that did not materially comport with the specifications of the FDA approval for those devices in violation" of the FCA and its New York state analogue), affirmed the dismissal of relators' other claims, and remanded the case to the district court. (#204 at 31.)

Relators' remaining claims are premised on the allegation "that DePuy falsely palmed off devices that, due to latent manufacturing defects, materially deviated from the design specification of the FDA-approved Pinnacle MoM device." (#204 at 6); *see also DePuy*, 865 F.3d at 32.[5]

[5] "One [alleged] defect [referred to as the diametrical clearance defect] occurred when the sizes as manufactured of the artificial femoral head and its acetabular cup caused them to fit too snugly, impeding the cushioning intervention of the bodily fluid that precluded the head and cup from rubbing directly against each other." (#204 at 6.) "The [alleged] second defect [referred to as the taper trunnion defect] occurred when the surface of the taper trunnion that interacted with the taper emerged from the manufacturing process with too much roughness. This roughness increased friction and the shedding of small metal debris when the trunnion moved against the taper." *Id.*

DePuy's alleged wrongdoing dates back to December 2000, when DePuy received FDA approval to market and sell the Pinnacle device under section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360e(b)(1)(B)(ii). (#204 at 5.) The approval process under section 510(k) "allows a device manufacturer to piggyback on the full-scale review and approval of another device by demonstrating that the new device is 'substantially equivalent to a predicate device' which itself may be marketed pending the completion of a full premarket approval process." *Id.* at 10 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 345 (2001)). While a device like the Pinnacle would ordinarily be required to undergo a more extensive premarket approval process, DePuy represented to the FDA that the Pinnacle was "substantially equivalent" to the ASR, which had previously received premarket approval. *Id.* at 5–6.

The parties filed a stipulated protective order of confidentiality in this action, which was approved by Judge Sorokin on January 8, 2018. (#249.) The stipulated protective order provided:

> 17. A party may not file or use any "PROTECTED DOCUMENT" or "PROTECTED DOCUMENT – ATTORNEYS' EYES ONLY" in any other action unless (a) the party is also subject to a protective order entered in that action which is the same or substantially similar to this protective order (although nothing in this Protective Order alters the January 5, 2015 ruling issued by the Honorable David A. Katz . . . ,) (b) the party receives written permission from the [s]upplying [p]arty[,] or (c) the party obtains an order from [] this [c]ourt secured after appropriate notice to all interested persons.

Id. ¶ 17. Although DePuy provided relators with all the discovery it produced in the MDL litigations – including information subject to confidentiality orders that relators had already received as experts – and the government received such information from relators for their investigation, the record is clear that DePuy never gave relators written "permission" to use any of

the confidential documents, including those subject to Judge Katz's order. *See* ##361-1 at 2; 365-1 at 2.

DePuy maintains that it initially took relators at their word that they had not used any confidential documents in drafting either their second amended complaint, or their corrected second amended complaint. (#397 at 3.) However, in December 2019, DePuy learned that relators gave QA Consulting (QA), their expert in this case, information they learned as experts in the ASR MDL litigation, so that QA could perform various statistical analyses relating to the failed Pinnacle implants. (##359 at 8 n.9; 397 at 3–4.) DePuy maintains that QA's analyses are "required to support key statistical allegations set forth in the [corrected second amended complaint]." (#376 at 3.)[6]

[6] Relators allege the following with respect to QA's statistical analyses:

> QA performed a statistical analysis of numerous failed Pinnacle explants. QA's analysis confirmed the inadequacy of DePuy's process for validating the manufacture of Pinnacle heads, cups, and liners. QA found that the components' high rate of diametrical clearance nonconformance had indicated that DePuy's manufacturing process had failed to satisfy basic industry and FDA standards of manufacturing integrity.
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> QA performed two statistical analyses of data maintained by [relator] Dr. Langton relating to failed Pinnacle implants. . . .
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> . . .
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> Based upon Dr. Langton's raw data – which was representative of the outcomes of DePuy's manufacturing process – QA concluded that the process was incapable of consistently producing Pinnacle cups, heads, and liners that would meet the diametrical clearance. The Ppk was .38 for the explant heads and 0.1 for the explant liners – both well below the minimum industry standard of 1.0.
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> Based upon QA's statistical analysis, DePuy's manufacturing process fails to produce implant heads within specifications 14.83% of the time and implant liners 50.41% of the time.

Relators maintain that they have not used confidential DePuy information to plead or otherwise prosecute the corrected second amended complaint. (#361 at 2.) DePuy counters that, due to relators' recent admission that relators gave QA material that was subject to Judge Katz's confidentiality order, "anything related to QA" is "eternally tainted" pursuant to Judge Saylor's order, and, therefore, must be stricken from DePuy's corrected second amended complaint. (#369 at 5–6); *see* ##101; 104 at 27. DePuy maintains that, once the QA-related allegations are stricken, the corrected second amended complaint "no longer would contain any assertions concerning the rate of DePuy's alleged non-compliance with manufacturing specifications." (#369 at 6–7.) Depuy posits that without these allegations, the corrected second amended complaint would not survive the pleading requirements of either Rule 12(b)(6) or Rule 9(b) and should be dismissed. *Id.* at 7.

DePuy also contends that relators have failed to respond to numerous discovery requests, regarding their relationship with QA, and the protocols, steps, and processes used to measure and analyze the Pinnacle MoM devices. In addition to determining whether relators did, in fact, violate Judge Katz's confidentiality order, DePuy maintains that the information sought is necessary to determine whether relator Langton's data can be validated, and to vet the statistical analyses

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> QA concluded that such pervasive failures in DePuy's quality controls required far greater scrutiny and monitoring of its manufacturing process. In order to ensure an acceptable rate of nonconformance under such conditions, QA concluded, DePuy's inspectors would have been required to adequately inspect each and every component contained in every production batch in order to ensure that their dimensions met the minimum standard of quality for sale in the marketplace . . . .
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> . . .
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> Based upon their analyses of explant data derived from the [r]etrieval [d]atabase, coupled with the analysis of their expert, QA, [r]elators allege that DePuy failed to [validate its manufacturing operations under one of the FDA's codified methods].

(#219 ¶¶ 344, 346, 348–50, 352–53; *see also* ¶ 422.)

relators and QA performed. (#351 at 20.) Information about what relators knew, and when they knew it, may also support potential materiality and public disclosure defenses, should the litigation reach the summary judgment stage. *Id.* at 42–43.

The parties also take issue with a December 10, 2019 scheduling order, where this court modified the discovery deadlines as follows:

> Completion of all document production: January 6, 2020;
> Completion of all other fact discovery: March 27, 2020;
> Relators' expert disclosures: April 27, 2020;
> Defendants' expert disclosures: June 26, 2020;
> Completion of expert discovery: July 28, 2020;
> Motions for summary judgment: September 21, 2020;
> Responses to motions for summary judgment: November 23, 2020;
> Reply briefs: January 26, 2021;
> Sur-reply briefs: February 26, 2021.

(#357 (citing #354 at 3–4).) The court's order made "clear that the new deadline for completion of document production, January 6, 2020, applie[d] to all documents, including third-party documents, not just those in relators' possession, custody or control." *Id.* The court's order also stated that "the court did not anticipate granting any further motions for extensions" (#357), as it had previously granted several of relators' motions to modify the scheduling order. *See, e.g.*, #341.

III. Discussion.

A. Judge Katz's order remains binding on relators.

Relators maintain that, while they have not used the confidential DePuy information to plead or otherwise prosecute the corrected second amended complaint, the DePuy information they received as experts is relevant to the present action, and Judge Katz's order should not be binding on them here. (##361 at 2; 386 at 9.) Relators request that the court clarify that, under paragraph seventeen of Judge Sorokin's protective order, "DePuy's agreement to produce all MDL discovery in this action constituted [DePuy's] 'written permission'" to use the information they received in

their capacities as experts in the MDL litigations to prosecute the present action. (#359 at 4 (citing #249 ¶ 17).)

Relators' request is denied. They are prohibited from using any of the information they received in their capacities as experts in the MDL litigations to prosecute the present case. Judge Katz's order makes clear that relators cannot use the confidential knowledge they received as experts "for their own benefit," (#103 at 17), and Judge Sorokin's January 2018 protective order explicitly states that "*nothing*" in the order altered Judge Katz's ruling. (#249 ¶ 17 (emphasis added)); *see also Ferrara & Dimercurio v. St. Paul Mercury*, 240 F.3d 1, 11–12 (D. Mass. 2016) (protective orders issued by other courts relating to previous litigation may be valid and binding).

Numerous communications from DePuy to relators make clear that DePuy never intended to allow relators to use confidential information in the present litigation. *See, e.g.*, #361-1 at 2 (stating that DePuy would not allow relators or their counsel to use the confidential documents in the qui tam action following Judge Katz's order); #365-1 at 2 (noting that, by providing the MDL discovery, DePuy had "in no way waived its arguments as to the scope and applicability of Judge Katz's order"). Relators cite no case law to support their argument that DePuy's production of the MDL discovery constituted permission to use the discovery going forward.

There is a dearth of First Circuit case law evaluating whether this court could modify another judge's confidentiality order such as Judge Katz's order, governing material relators received as experts in separate litigation. Regardless whether Judge Katz's order must be considered legally binding on relators in the present case, equity demands that it should be. As Judge Katz explained in his well-reasoned order, allowing relators to use confidential information in this litigation, which would not have been available to them but for their role as experts in the ASR MDL litigation, would create distrust between parties exchanging confidential information

in future, similar litigation. (#103 at 15–16.) Defendants "would become very hesitant" in sharing confidential discovery materials if the plaintiffs' experts could then use their "positions of trust to their benefit and [defendants'] detriment[.]" *Id.* at 16–17. In essence, the confidentiality orders the parties previously relied on would be "for naught." *Id.* at 17.

B. DePuy is entitled to receive from relators the discovery materials allegedly subject to Judge Katz's confidentiality order.

Relators request that the court clarify whether its document production must include the confidential documents relators generated using the information they received in their capacities as MDL experts, and documents that were "informed by" the information they received as experts. (#359 at 4, 10.) Relators maintain that it is a double standard to prohibit them from using the documents they received in their capacity as MDL experts, while simultaneously compelling them to "produce this very same information for [DePuy's] own use . . . ." (#359 at 11.)

Relators must provide all materials they gave to QA in the present case, including information they generated or received as experts in the MDL litigation, and indicate when each piece of information was provided to QA. DePuy is also permitted to depose Holland of QA as a fact witness, for the limited purpose of determining what information was produced and when. As DePuy points out, the Katz order did not set a boundary of any kind on the relators' obligations to produce documents responsive to discovery requests in this action. (#360 at 3.) Moreover, withholding that information from DePuy would be nonsensical, as DePuy was the originator of the information in the MDL litigation. Knowing which of the confidential DePuy documents were provided to QA, and when, will enable DePuy to determine whether relators violated Judge Katz's confidentiality order, and, if so, file any appropriate motion to strike or dismiss.[7]

[7] Relators will be permitted to use the confidential documents they generated as experts to prosecute the case, if it is determined that relators did not violate Judge Katz's order and the case continues. *See* #360 at 9 ("DePuy agrees that to the extent this action continues, [r]elators would

C. Relators must provide any additional relevant documents.

Relators must also provide any additional documents regarding their relationship with QA, and the protocols, steps, and processes used to measure and analyze the Pinnacle MoM devices. Assuming that there was no violation of Judge Katz's confidentiality order and the case survives a motion to dismiss, these documents are relevant to potential materiality or public disclosure defenses.[8]

V. Conclusion.

Relators' motion for clarification (#358) is granted to the extent that Judge Sorokin's protective order and the December 10, 2019 scheduling order are clarified in this Memorandum, and otherwise, denied. DePuy's motion to compel (#387) is granted to the following extent: relators shall produce the DePuy materials subject to Judge Katz's confidentiality order, and any other documents not already produced concerning relators' relationship with QA, and the

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be permitted to use . . . all documents produced to [r]elators by DePuy in this action, including during summary judgment briefing and at trial. This would include documents to which [r]elators previously had access only in their capacity as experts in the MDL litigations.")

[8] The Supreme Court has made clear that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the" FCA. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). Materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* at 2003 (citing *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943)). "[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 2003–04. Therefore, DePuy's ability to vet the statistical calculations relators and QA performed to determine the percentage of time the Pinnacle devices deviated from the manufacturing specifications is critical. *See* #351 at 16–17 (noting, as an example, that it would likely be much easier for relators to show materiality if there was a manufacturing defect 50% of the time versus 10% of the time).

The FCA also "precludes jurisdiction over suits whose allegations of fraud are based on publicly disclosed information, unless the realtor was the 'original source' of the information." *Leysock v. Forest Labs*, No. 12-11354-FDS, 2017 U.S. Dist. LEXIS 65048, at *12 (D. Mass. Apr. 28, 2018) (citing *U.S. ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 681 (1st Cir. 1997)).

protocols, steps, and processes used to measure and analyze DePuy's Pinnacle MoM devices by August 31, 2020; relators are to provide answers to the questions DePuy raised during the parties' February 10, 2020, meet-and-confer call by July 30, 2020; and relators shall provide supplemental answers for any interrogatory that requires supplementation by August 31, 2020. Further action on the motion to compel (#387) is pretermitted at this time.

Relators shall prepare and serve their final privilege logs by July 30, 2020. All remaining document production, which applies to all documents, including third-party documents, not just those in relators' possession, custody, or control, shall be completed by August 31, 2020.

/s/ Page Kelley
Page Kelley
Chief United States Magistrate Judge

July 8, 2020